

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

Kasid et al.

Group Art Unit: Unassigned

Application No. Unassigned

Examiner: Unassigned

Filed: July 25, 2003

For: ANTI-APOTOPIC GENE SCC-S2 AND  
DIAGNOSTIC AND THERAPEUTIC  
USES THEREOF

**INFORMATION DISCLOSURE STATEMENT**

Mail Stop Patent Application  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Pursuant to 37 CFR 1.97 and 1.98, the references listed on the enclosed Form PTO-1449 and/or Substitute Form PTO-1449 ("Form 1449") are submitted for consideration by the Examiner in the examination of the above-identified patent application.

The full consideration of the references in their entirety by the Examiner is respectfully requested and encouraged. Also, it is respectfully requested that the references be entered into the record of the present application and that the Examiner place his or her initials in the appropriate area on the enclosed Form 1449, thereby indicating the Examiner's consideration of each of the references.

The submission of the references listed on the Form 1449 is for the purpose of providing a complete record and is not a concession that the references listed thereon are prior art to the invention claimed in the patent application. The right is expressly reserved to establish an invention date earlier than the above-identified filing date in order to remove any reference submitted herewith as prior art should it be deemed appropriate to do so.

Further, the submission of the references is not to be taken as a concession that any reference represents art that is relevant or analogous to the claimed invention. Accordingly, the right to argue that any reference is not properly within the scope of prior art relevant to an examination of the claims in the above-identified application is also expressly reserved.

The Information Disclosure Statement is being filed:

- ☒ **within** any one of the following time periods: (a) within three months of the filing date of a national application other than a continued prosecution application under 37 CFR 1.53(d); (b) within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 of an international application; (c) before the mailing date

In re Appln. of Kasid et al.  
Application No. Unassigned

of a first Office Action on the merits; or (d) before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

- ☐ **after** (a), (b), (c) or (d) above, but before the mailing date of a final action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and includes *one* of:

☐ the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below).

*or*

☐ the fee of \$180 set forth in 37 CFR 1.17(p) (see "Fees" below).

- ☐ **after** the mailing date of a final action under 37 CFR 1.113 or a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and on or before payment of the issue fee, and includes the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).

- ☐ **after** the mailing date of a Notice of Allowance under 37 CFR 1.311, and on or before payment of the issue fee, and **within** thirty days of receiving each item of information contained in the Information Disclosure Statement, and includes the Statement under 37 CFR 1.704(d) (see "Statement under 37 CFR 1.704(d)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).

NOTE: This is for original applications except applications for a design patent, filed on or after May 29, 2000, wherein a paper containing only an Information Disclosure Statement in compliance with 37 CFR 1.97 and 1.98 is being filed.

### Copies of the References

- ☒ Copies of the references listed on the enclosed Form 1449 are enclosed herewith. Attached to each reference not in the English language is a concise explanation of the relevance pursuant to 37 CFR 1.98(a)(3). An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of the relevance pursuant to 37 CFR 1.98(a)(3).

- ☒ A copy of the foreign search report is enclosed herewith.

- ☐ The references listed on the enclosed Form 1449 were previously identified in the parent application(s) of the present application, and copies of the references were furnished at that time. Accordingly, additional copies of the references are not submitted herewith, so as not to burden the file with duplicate copies of references. The Examiner is respectfully requested to carefully review the references in accordance with the requirements set out in the Manual of Patent Examining Procedure. In accordance with 37 CFR 1.98(d), the details of the parent application(s) relied upon for an earlier filing date under 35 USC 120 in which copies of the references were previously furnished are set out below:

In re Appln. of Kasid et al.  
Application No. Unassigned

| U.S. APPLICATIONS |                  | Status ( <i>check one</i> ) |         |           |
|-------------------|------------------|-----------------------------|---------|-----------|
| U.S. APPLICATIONS | U.S. FILING DATE | PATENTED                    | PENDING | ABANDONED |
| 1.                |                  |                             |         |           |
| 2.                |                  |                             |         |           |
| 3.                |                  |                             |         |           |

**Statement under 37 CFR 1.97(e)**

- ☐ The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.
- ☐ The **undersigned** hereby states that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

**Statement under 37 CFR 1.704(d)**

- ☐ The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in 37 CFR 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

**Fees**

- ☒ No fee is owed by the applicant(s).
- ☐ The **IDS Fee of \$180** under 37 CFR 1.17(p) is enclosed herewith.

**Method of Payment of Fees**

- ☐ Attached is a check in the amount of \$ .
- ☐ Charge Deposit Account No. 12-1216 in the amount of \$ . (A duplicate copy of this communication is enclosed for that purpose.)

**Authorization to Charge Additional Fees**

- ☒ If any additional fees are owed in connection with this communication, please charge Deposit Account No. 12-1216. (A duplicate copy of this communication is enclosed for that purpose.)

In re Appln. of Kasid et al.  
Application No. Unassigned

**Instructions as to Overpayment**


☒  
☐

Credit Account No. 12-1216.  
Refund

A handwritten signature in black ink, appearing to read 'M. Daniel Hefner', is written over a horizontal line.

M. Daniel Hefner, Reg. No. 41,826  
LEYDIG, VOIT & MAYER, LTD.  
Two Prudential Plaza, Suite 4900  
180 North Stetson  
Chicago, Illinois 60601-6780  
(312) 616-5600 (telephone)  
(312) 616-5700 (facsimile)

Date: July 25, 2003

Please type a plus sign (+) inside this box → 

|  |   |    |   |                          |               |
|--|---|----|---|--------------------------|---------------|
| Substitute for form 1449A/B/PTO<br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(Use as many sheets as necessary) |   |    |   | <b>Complete if Known</b> |               |
|  |   |    |   | Application Number       | Unassigned    |
|  |   |    |   | Filing Date              | July 25, 2003 |
|  |   |    |   | First Named Inventor     | Kasid et al.  |
|  |   |    |   | Group Art Unit           | Unassigned    |
|  |   |    |   | Examiner Name            | Unassigned    |
| Sheet  | 1 | of | 3 | Attorney Docket Number   | 223316        |

| U.S. PATENT DOCUMENTS |             |                                 |           |                               |                        |                               |
|-----------------------|-------------|---------------------------------|-----------|-------------------------------|------------------------|-------------------------------|
| Examiner<br>Initials  | Doc.<br>No. | U.S. Patent Document            |           | Name of Patentee or Applicant | Date of<br>Publication | Filing Date If<br>Appropriate |
|                       |             | Application or<br>Patent Number | Kind Code |                               |                        |                               |
|                       | AA          | 5,801,154                       |           | Baracchini et al.             | Sept. 1, 1998          |                               |
|                       |             |                                 |           |                               |                        |                               |
|                       |             |                                 |           |                               |                        |                               |

| OTHER - NON PATENT LITERATURE DOCUMENTS |             |   |             |      |  |
|---|-------------|---|-------------|------|--|
| Examiner<br>Initials                    | Doc.<br>No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.                    | Translation |      |  |
|   |             |   | Yes         | No** |  |
|   | AB          | AGRAWAL, "Importance of nucleotide sequence and chemical modifications of antisense oligonucleotides," <i>Biochimica et Biophysica Acta</i> 1489, 53-68 (1999)  |             |      |  |
|   | AC          | ASHKENAZI et al., "Death Receptors: Signaling and Modulation," <i>Science</i> , 281 (5381), 1305-1308 (1998)  |             |      |  |
|   | AD          | BERTIN et al., "Death effector domain-containing herpesvirus and poxvirus proteins inhibit both Fas- and TNFR1-induced apoptosis," <i>Proceedings of the National Academy of Sciences of the United States of America</i> , 94 (4), 1172-1176 (1997)                                |             |      |  |
|   | AE          | BLUNDELL et al., "Knowledge-based prediction of protein structures and the design of novel molecules," <i>Nature</i> , 326 (6111), 347-352 (1987)   |             |      |  |
|   | AF          | BOLDIN et al., "Involvement of MACH, a Novel MORT1/FADD-Interacting Protease, in Fas/APO-1- and TNF Receptor-Induced Cell Death," <i>Cell</i> , 85 (6), 803-815 (1996)  |             |      |  |
|   | AF          | CHINNAIYAN et al., "FADD/MORT1 Is a Common Mediator of CD95 (Fas/APO-1) and Tumor Necrosis Factor Receptor-induced Apoptosis," <i>The Journal of Biological Chemistry</i> , 271 (9), 4961-4965 (1996)   |             |      |  |
|   | AG          | CHIOU et al., "Inhibition of ICE-like Proteases Inhibits Apoptosis and Increases Virus Production during Adenovirus Infection," <i>Virology</i> , 244 (1), 108-118 (1998)   |             |      |  |
|   | AH          | CORPET, "Multiple sequence alignment with hierarchical clustering," <i>Nucleic Acids Research</i> , 16 (22), 10881-10890 (1988)   |             |      |  |
|   | AI          | CROOKE, "Molecular mechanisms of action of antisense drugs," <i>Biochimica et Biophysica Acta</i> 1489, 31-44 (1999)  |             |      |  |
|   | AJ          | DARZYNKIEWICZ et al., "Features of Apoptotic Cells Measured by Flow Cytometry," <i>Cytometry</i> , 13 (8), 795-808 (1992)   |             |      |  |
|   | AK          | EARL et al., "Homology between DNA polymerases of poxviruses, herpesviruses, and adenoviruses: Nucleotide sequence of the vaccine virus DNA polymerase gene," <i>Proceedings of the National Academy of Sciences of the United States of America</i> , 83 (11), 3659-3663 (1986)    |             |      |  |
|   | AL          | GOKHALE et al., "Antisense <i>raf</i> Oligodeoxyribonucleotide Is a Radiosensitizer <i>In Vivo</i> ," <i>Antisense &amp; Nucleic Acid Drug Development (The Antisense Journal)</i> , 9 (2), 191-201 (1999)  |             |      |  |
|   | AM          | GOLTSEV et al., "CASH, a Novel Caspase Homologue with Death Effector Domains," <i>The Journal of Biological Chemistry</i> , 272 (32), 19641-19644 (1997)  |             |      |  |
|   | AN          | GRIFFITH et al., "Intracellular Regulation of TRAIL-Induced Apoptosis in Human Melanoma Cells," <i>The Journal of Immunology</i> , 161 (6), 2833-2840 (1998)  |             |      |  |
|   | AO          | HAN et al., "Suppression of <i>In Vivo</i> Tumorigenicity of Human Lung Cancer Cells by Retrovirus-mediated Transfer of the Human Tumor Necrosis Factor- $\alpha$ cDNA," <i>Respiratory Cell and Molecular Biology</i> , 11 (3), 270-278 (1994)                                     |             |      |  |
|   | AP          | HEO et al., "Biology, Cytogenetics, and Sensitivity to Immunological Effector Cells of New Head and Neck Squamous Cell Carcinoma Lines," <i>Cancer Research</i> , 49 (18), 5167-5175 (1989)   |             |      |  |
|   | AQ          | HORREVOETS et al., "Vascular Endothelial Genes That Are Responsive to Tumor Necrosis Factor- $\alpha$ <i>In Vitro</i> Are Expressed in Atherosclerotic Lesions, Including Inhibitor of Apoptosis Protein-1, Stannin, and Two Novel Genes," <i>Blood</i> , 93 (10), 3418-3431 (1999) |             |      |  |

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet

2

of

2

**Complete if Known**

|                        |               |
|------------------------|---------------|
| Application Number     | Unassigned    |
| Filing Date            | July 25, 2003 |
| First Named Inventor   | Kasid et al.  |
| Group Art Unit         | Unassigned    |
| Examiner Name          | Unassigned    |
| Attorney Docket Number | 223316        |

**OTHER - NON PATENT LITERATURE DOCUMENTS**

| Examiner Initials | Doc. No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.  | Translation |      |
|-------------------|----------|---|-------------|------|
|                   |          |   | Yes         | No** |
|                   | A R      | HU et al., "A Novel Family of Viral Death Effector Domain-containing Molecules That Inhibit Both CD-95- and Tumor Necrosis Factor Receptor-1-induced Apoptosis," <i>The Journal of Biological Chemistry</i> , 272 (15), 9621-9624 (1997)  |             |      |
|                   | A S      | HU et al., "I-FLICE, a Novel Inhibitor of Tumor Necrosis Factor Receptor-1- and CD-95-induced Apoptosis," <i>The Journal of Biological Chemistry</i> , 272 (28), 17255-17257 (1997)   |             |      |
|                   | A T      | HU et al., "Adenovirus E1B 19K Protein Is Required for Efficient DNA Replication in U937 Cells," <i>Virology</i> , 227 (2), 295-304 (1997)  |             |      |
|                   | A U      | INBAL et al., "DAP kinase links the control of apoptosis to metastasis," <i>Nature</i> , 390 (6656), 180-184 (1997)   |             |      |
|                   | A V      | IRMLER et al., "Inhibition of death receptor signals by cellular FLIP," <i>Nature</i> , 388 (6638), 190-195 (1997)  |             |      |
|                   | A W      | KASID et al., "Stress-responsive signal transduction: emerging concepts and biological significance," APOTOSIS GENES, Kluwer Academic Publishers, Boston, Chapter 4, pp. 85-117 (1998)  |             |      |
|                   | A X      | KASID et al., "Ionizing radiation and TNF- $\alpha$ stimulate gene expression of a Thr/Tyr-protein phosphatase HVH1 and inhibitory factor IKB $\alpha$ in human squamous carcinoma cells," <i>Molecular and Cellular Biochemistry</i> , 173 (1 & 2), 193-197 (1997)   |             |      |
|                   | A Y      | KASID et al., "Effect of Antisense c-raf-1 on Tumorigenicity and Radiation Sensitivity of a Human Squamous Carcinoma," <i>Science</i> , 243 (4896), 1354-1356 (1989)  |             |      |
|                   | A Z      | KATAOKA et al., "FLIP Prevents Apoptosis Induced by Death Receptors But Not by Perforin/Granzyme B, Chemotherapeutic Drugs, and Gamma Irradiation," <i>The Journal of Immunology</i> , 161 (8), 3936-3942 (1998)  |             |      |
|                   | B A      | KISSIL et al., "Structure-function analysis of an evolutionary conserved protein, DAP3, which mediates TNF- $\alpha$ - and Fas-induced cell death," <i>The EMBO Journal</i> , 18 (2), 353-362 (1999)  |             |      |
|                   | B B      | KUMAR et al., "Identification of a Novel Tumor Necrosis Factor- $\alpha$ -inducible Gene, SCC-S2, Containing the Consensus Sequence of a Death Effector Domain of Fas-associated Death Domain-like Interleukin-1 $\beta$ -converting Enzyme-inhibitory Protein," <i>The Journal of Biological Chemistry</i> , 275 (4), 2973-2978 (2000) |             |      |
|                   | B C      | LENNON et al., "The I.M.A.G.E. Consortium: An Integrated Molecular Analysis of Genomes and Their Expression," <i>GENOMICS</i> , 33 (1), 151-152 (1996)  |             |      |
|                   | B D      | MILNER et al., "Selecting effective antisense reagents on combinatorial oligonucleotide arrays," <i>Nature Biotechnology</i> , 15, 537-541 (1997)   |             |      |
|                   | B E      | MORIMOTO et al., "Synergistic Effect of Tumor Necrosis Factor- $\alpha$ - and Diphtheria Toxin-Mediated Cytotoxicity in Sensitive and Resistant Human Ovarian Tumor Cell Lines," <i>The Journal of Immunology</i> , 147 (8), 2609-2616 (1991)   |             |      |
|                   | B F      | MUZIO et al., "FLICE, A Novel FADD-Homologous ICE/CED-3-like Protease, Is Recruited to the CD95 (Fas/APO-1) Death-Inducing Signaling Complex," <i>Cell</i> , 85 (6) 817-827 (1996)  |             |      |
|                   | B G      | NAKAI et al., "A Knowledge Base for Predicting Protein Localization Sites in Eukaryotic Cells," <i>GENOMICS</i> , 14, 897-911 (1992)  |             |      |
|                   | B H      | NICOLETTI et al., "A rapid and simple method for measuring thymocyte apoptosis by propidium iodide staining and flow cytometry," <i>Journal of Immunological Methods</i> , 139 (2), 271-279 (1991)  |             |      |
|                   | B I      | ODA et al., "Cloning of the Human $\alpha$ -Catenin cDNA and its Aberrant mRNA in a Human Cancer Cell Line," <i>Biochemical and Biophysical Research Communications</i> , 193 (3), 897-904 (1993)   |             |      |
|                   | B J      | PATEL et al., "Constitutive Modulation of Raf-1 Protein Kinase is Associated with Differential Gene Expression of Several Known and Unknown Genes," <i>Molecular Medicine, Official Journal of the Molecular Medicine Society</i> , 3 (10), 674-685 (1997)  |             |      |

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet

3

of

3

## Application Number

Unassigned

Filing Date

July 25, 2003

**First Named Inventor**

Kasid et al.

Group Art Unit

Unassigned

**Examiner Name**

Unassigned

Attorney Docket Number

223316

Examiner  
Initials

Doc.  
No

### Translation

Yes

 $\text{No}^{++}$ 

BK

PATEL et al., "Identification of Seven Differentially Displayed Transcripts in Human Primary and Matched Metastatic Head and Neck Squamous Cell Carcinoma Cell Lines: Implications in Metastasis and/or Radiation Response," *Oral Oncology*, 33 (3), 197-203 (1997)

BL

SACCHI et al., "Antiproliferative Effects of Cytokines on Squamous Cell Carcinoma," *Archives of Otolaryngology-Head & Neck Surgery*, 117 (3), 321-326 (1991)

BM

SATA et al., "Endothelial Cell Apoptosis Induced by Oxidized LDL Is Associated with the Down-regulation of the Cellular Caspase Inhibitor FLIP," *The Journal of Biological Chemistry*, 273 (50), 33103-33106 (1998)

BN

SRINIVASULA et al., "FLAME-1 a Novel FADD-like Anti-apoptotic Molecule That Regulates Fas/TNFR1-induced Apoptosis," *The Journal of Biological Chemistry*, 272 (30), 18542-18545 (1997)

BO

STEIN, "Two problems in antisense biotechnology: in vitro delivery and the design of antisense experiments," *Biochimica et Biophysica Acta* 1489, 45-52 (1999)

BP

TEWARI et al., "CrmA, a Poxvirus-encoded Serpin, Inhibits Cytotoxic T-lymphocyte-mediated Apoptosis," *The Journal of Biological Chemistry*, 270 (39), 22705-22708 (1995)

BQ

THOME et al., "Viral FLICE-inhibitory proteins (FLIPs) prevent apoptosis induced by death receptors," 386 (6624), 517-521 (1997)

BR

TROPPMAIR et al., "v-Raf/v-Myc Synergism in Abrogation of IL-13 Dependence: v-Raf Suppresses Apoptosis," Mechanisms in B-Cell Neoplasia 1992, Workshop at the National Cancer Institute, National Institutes of Health, Bethesda, Maryland, 453-460 (1992)

BS

WEISS et al., "Human Herpesvirus Type 8 and Kaposi's Sarcoma," *Mongraphs Journal of the National Cancer Institute*, (23), 51-54 (1998)

BT

YEH et al., "Mitogen-activated Protein Kinase Kinase Antagonized Fas-associated Death Domain Protein-mediated Apoptosis by Induced FLICE-inhibitory Protein Expression," *The Journal of Experimental Medicine*, 188 (10), 1795-1802 (1998)

**Examiner Signature**

Date Considered

- \* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).
- + An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).